

### **REMARKS**

Upon entry of the present amendment, claims 11-24 will be pending. New claims 23 and 24 have been added and are fully supported by the instant specification as filed. No new matter has been added.

#### ***Rejection Under 35 U.S.C. § 103(a)***

Claims 1-22 have been rejected for alleged obviousness over U.S. Pat. No. 5,712,295 to Mencke et al. (“the U.S. Mencke patent”) in view of WO 96/38165 to Mencke et al. (“the Mencke publication”) *or* U.S. Pat. No. 4,199,569 to Chabala, et al. (“the Chabala patent”). The U.S. Mencke patent is said to disclose methods for treating endoparasitic infections with agonists and antagonists of the nicotinergic acetyl-choline receptors. The Mencke publication is said to disclose methods of treating endoparasitic infections with avermectins or milbemycin, including moxidectin. The Chabala patent is said to disclosed methods of treating ectoparasitic infections with avermectins. The Office has contended that “it would have been *prima facie* obvious . . . to treat a subject having both an endoparasitic infection and an ectoparasitic infection with a combination of a known anti-endoparasitic agent and a known anti-ectoparasitic agent because [one skilled in the art] would have expected that said combination would be effective for the treatment of both infections” (6/19/09 Office Action at page 3). In alleged support of this contention, the Office cites page 2, lines 16-19 of the present application, which states that at that the time the present application was filed, it was customary to protect pets against both endoparasites and ectoparasites by providing parenteral or oral treatment against the former and dermal treatment against the latter (*Id.*). The Office’s posited reasoning, however, makes unwarranted extensions of this reported practice to allegedly derive the present invention; the Office’s action is not supported by any teaching or suggestion in the cited art.

First, although it was known to treat both endoparasites and ectoparasites in the same animal, it was only known to do so using *two different* treatment types: one via oral administration and one via dermal modality. There is no teaching or suggestion in the cited references that one could modify the customary approach of using two different treatment types in a single animal by using a single treatment type (*e.g.*, dermal only or oral

administration only). Indeed, the present application discloses the first method for treating both endoparasites and ectoparasites using a single treatment modality. Accordingly, the Office has made an assumption about what would have allegedly been obvious, absent the benefit of impermissible hindsight provided by the Applicants' own disclosure, that is not supported by any teaching or suggestion of record. Assumptions of this kind cannot support a proper *prima facie* case of obviousness. *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (obviousness cannot be established based on a combination of references absent "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements ***in the way the claimed new invention does***") (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007); emphasis added).

Furthermore, even if it would have been obvious to use a single treatment type in order to administer both a medicament that is effective against endoparasites and a medicament that is effective against ectoparasites to a single animal (a point that, as discussed above, is not conceded by the Applicants), there is no evidence of record to suggest that it would have been obvious to combine both medicaments *into a single composition*, as recited in the present claims. Thus, not only has the Office drawn an unsupported conclusion regarding the alleged obviousness of using a single treatment type in order to treat both endo- and ectoparasites, but it is also inherent in the rejection of the pending claims for alleged obviousness that the Office has included a second assumption that is not supported by any evidence of record (*i.e.*, that it would necessarily have been obvious to combine both of the medicaments delineated above into a single composition). Absent particular evidence or reasoning to support this conclusion, the rejection for alleged obviousness is improper for this reason as well.

Moreover, even if it were assumed that it would have been obvious **not only** to use a single treatment type in order to administer one medicament effective against endoparasites and another effective against ectoparasites to a single animal, **but also** to combine both medicaments into a single composition (neither point being conceded by the Applicants), there remain two additional problems with the Office's position: The Office has not identified any evidence or reasoning to support the further assumption/contention that one of ordinary skill in the art would have combined or modified the cited prior art in the posited manner; or, that even if the combination were made, it would produce the claimed invention.

The art at issue is the U.S. Mencke patent, the Mencke publication, and the Chabala patent. The Office has posited two art combinations that allegedly make the claims obvious: the combination of the U.S. Mencke patent and the Mencke publication; or the combination of the U.S. Mencke patent and the Chabala patent. (6/19/09 Office Action at page 2, final paragraph).

First, even if one of ordinary skill in the art were so motivated (a point not conceded by the Applications), combination of the respective teachings of the U.S. Mencke patent and the Mencke publication would not result in any aspect of the claimed invention. Both references disclose the use of certain compounds for the treatment of *endoparasitic* infections. The present claims are directed to methods for the treatment of an animal having both an endoparasitic infection and an ectoparasitic infection. Neither the U.S. Mencke patent nor the Mencke publication teaches or suggests treatment of an animal having an ectoparasitic infection, much less an animal having an endoparasitic infection *and* an ectoparasitic infection. Any hypothetical combination of the teachings of the U.S. Mencke patent with those of the Mencke publication would result in the use of a composition comprising “at least one avermectin, [ivermectins,] or milbemycin . . . in combination with cyclic depsipeptides” (per the U.S. Mencke patent; *see, e.g.*, col. 2, lines 35-41) plus “agonists and antagonists of the nicotinergerg acetylcholine receptors” (per the Mencke publication) in a method for the treatment of *endoparasites* only. The Office has not presented any objective evidence or reasoning to show that one of ordinary skill in the art would apply the resulting combination to the treatment of ectoparasites. Absent such evidence or reasoning, a *prima facie* case of obviousness has not been presented, and the rejection of the claims over the U.S. Mencke patent and the Mencke publication is improper and should be withdrawn. *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974) (to establish a *prima facie* case of obviousness, all claim limitations must be taught or suggested by the prior art).

Additionally, there is no evidence or reasoning to support the contention that one of ordinary skill in the art would have combined the U.S. Mencke patent and the Chabala patent in order to produce the claimed invention. Previously, the Office had contended that the alleged rationale for combining the cited references was provided by the case *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA 1980). *Kerkhoven* states that “[i]t is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for

the same purpose, *in order to form a third composition to be used for the very same purpose*” (emphasis added). However, the holding of *In re Kerkhoven* is not applicable to the posited combination of the U.S. Mencke patent and the Chabala patent, and in fact a *prima facie* case of obviousness has not been presented, at least because the two references cannot be said to teach “two compositions each of which is taught . . . to be useful for the same purpose”, and because the resulting combination would not be said “to be useful for the very same purpose,” as required by that court decision. More specifically, while the U.S. Mencke patent discloses compositions that are said to be effective against *endoparasites*, the Chabala patent discloses compositions that are said to be useful for a *different* purpose, *i.e.*, for treatment against *ectoparasites*. Likewise, any combination of the compounds of the U.S. Mencke patent with those of the Chabala patent would not “form a third composition to be useful *for the very same purpose* [as the constituent compounds]”, because the resulting “third” composition would not be for treatment of *only endoparasites* and would not be for treatment of *only ectoparasites*. Thus, the *Kerkhoven* case does not apply to the posited combination of the U.S. Mencke patent and the Chabala patent. And, as no other objective evidence or reasoning has been presented by the Office in support of its contention, a *prima facie* case of obviousness has not been established. As such, any rejection of the present claims over the U.S. Mencke patent and the Chabala patent is improper and should be withdrawn. *See, e.g., Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (obviousness cannot be established based on a combination of references absent “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does*”) (citing *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007); emphasis added).

### ***New Claims***

New claims 23 and 24 have been added. Like independent claims 1 and 17, each discloses a method for treating an animal having both an endoparasitic infection and an ectoparasitic infection, and for at least the reasons provided above, are likewise allowable over the prior art of record.

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**PATENT**

***Conclusion***

Applicants believe that the foregoing constitutes a complete and full response to the pending Office Action and that the pending claims are in condition for allowance. Accordingly, an indication of allowability of the pending claims is respectfully requested.

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